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(71) Applicant: ADVANCED CARDIOVASCULAR SYSTEMS, INC. [US/US]; 3200 Lakeside Drive, Santa Clara, CA 95054-2807 (US).

(72) Inventors: HARRISON, William, J.; 32257 Cour Meyney, Temecula, CA 92591 (US). STACK, Richard, S.; 106 Alder Place, Chapel Hill, NC 27514 (US). STALKER, Kent, C., B.; 702 Pascali Court, San Marcos, CA 92069 (US).

(74) Agents: HANKE, Gunther, O. et al.; Fulwider Patton Lee & Utecht, LLP., Howard Hughes Center, Tenth floor, 6060 Center Drive, Los Angeles, CA 90045 (US).

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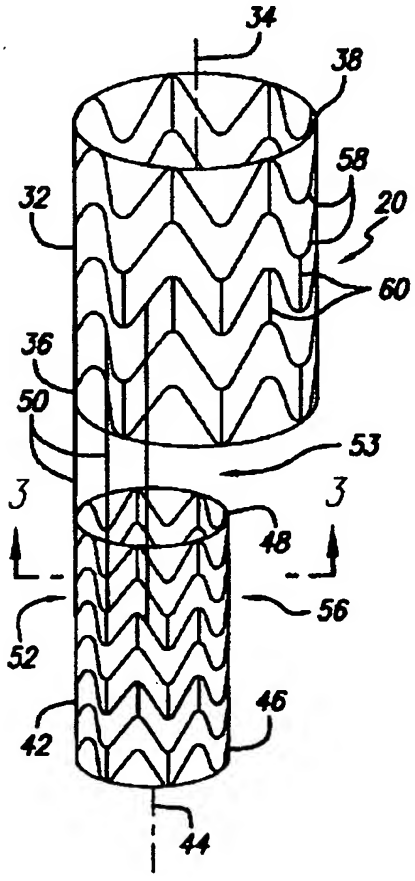
(54) Title: BIFURCATED STENT SYSTEM



(57) Abstract: The self-expanding stent assembly is formed of discrete stent sections expandable to different diameters to accomodate a trunk or main vessel portion and one or more side branch portions of a bifucarted blood vessel. The discrete stent sections are spaced apart by a gap allowing blood flow between the sections from the trunk or main vessel portion to the side branch portions of the bifurcated blood vessel, and are connected together by one or more longitudinal spines. The stent assembly is adapted to be placed within bifurcated blood vessels at the point of bifurcation, with a larger section being adapted to be disposed within the main body or trunk or main vessel portion of the bifurcation, and one or more smaller sections being adapted to be disposed within one or more of the branches of the bifurcated blood vessel. The sections of the stent assembly are preferably formed from a self-expanding material so that the stent sections expand from a first smaller diameter for delivery through a body lumen to a second expanded diameter for implantation in the bifurcated blood vessel.

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BIFURCATED STENT SYSTEM

BACKGROUND OF THE INVENTION

Field of the Invention:

This invention relates generally to self-expanding stent assemblies for use at and around a bifurcation of bifurcated blood vessels, and more particularly concerns a segmented bifurcated stent assembly for repairing lesions at and around the bifurcation of the bifurcated blood vessels.

Description of Related Art:

Stents are typically implanted within a vessel in a contracted state and expanded when in place in the vessel in order to maintain patency of the vessel to allow fluid flow through the vessel. Implantation of such stents is commonly accomplished by mounting the stent on the balloon portion of a catheter, positioning the stent in a body lumen, and expanding the stent to an expanded state by inflation of a balloon within the stent. The stent can then be left in place by deflating the balloon and removing the catheter. An alternate approach is to utilize a self-expanding stent that is introduced in a collapsed state, so that when properly positioned, a retaining sheath can be withdrawn, and the stent can be allowed to expand into position.

A bifurcated stenosis typically can occur in the carotid or coronary arteries at the carina between adjoining arterial branches and around the ostia of the adjoining arterial branches. Employment of a stent for repair of vessels that are diseased at a bifurcation requires that the stent must, without compromising blood flow, overlay at least a portion of the circumference of the ostium to a diseased portion and extend to a point within and beyond the diseased portion. Particularly at a bifurcation, lesions may form along the side walls of the blood vessel and at the carina of the bifurcation, not only contributing to stenosis of a main branch and side branch of the bifurcation, but also interfering with the normal blood flow at the bifurcation, to create eddy currents that can contribute to formation of thrombosis.

Conventional stents are designed to repair areas of blood vessels that are removed from bifurcations and, since a conventional stent generally terminates at right angles to its longitudinal axis, the use of conventional stents in the region of a vessel bifurcation may result in blocking blood flow of a side branch. For example, such a conventional stent might be

placed so that a portion of the stent extends into the pathway of blood flow to a side branch of the bifurcation or extend so far as to completely cover the path of blood flow in a side branch. The conventional stent might alternatively be placed proximal to, but not entirely overlaying the circumference of the ostium to the diseased portion. However, such a positioning of a conventional stent will result in a bifurcation that is not completely repaired.

The delivery of bifurcated stents at a treatment site of a bifurcated blood vessel has heretofore presented numerous problems. In one method, a main vessel stent is implanted at the bifurcation across a side branch, and the structure of main vessel stent must be spread apart sufficiently to form an opening to the side branch vessel for a catheter with a stent for the side branch to be delivered through the opening. The portion of the structure of the main vessel stent to be spread apart is typically selected by trial and error by crossing and recrossing the structure of the main vessel stent with a wire. In addition, the aperture created through the main vessel stent may not provide a clear opening and can create a major distortion in the surrounding structure of the stent.

In another similar conventional method for treating bifurcated vessels, the side-branch vessel is first stented so that the stent protrudes into the main vessel. A dilatation is then performed in the main vessel to open and stretch the stent struts extending across the lumen from the side-branch vessel. Thereafter, the main-vessel stent is implanted so that its proximal end overlaps with the side-branch vessel. However, the structure of the deployed stent must be recrossed with a wire by trial and error.

In another prior art procedure, known as "kissing" stents, a stent is implanted in the main vessel with a side-branch stent partially extending into the main vessel creating a double-barreled lumen of the two stents in the main vessel. Another prior art approach includes a so-called "trouser legs and seat" approach, which includes implanting three stents, one stent in the side-branch vessel, a second stent in a distal portion of the main vessel, and a third stent, or a proximal stent, in the main vessel just proximal to the bifurcation.

The prior art stents for treating bifurcations are also difficult to use, making successful placement nearly impossible. Further, even where placement of stents at a bifurcation has been successful, it is difficult to precisely control the spacing between multiple stents at or around the bifurcation of bifurcated blood vessels to allow for proper blood flow at the bifurcation. In addition to the above mentioned problems, the two branches of a bifurcation often differ significantly in diameter. Ideally, the branches of a self-expanding bifurcated stent

should automatically expand to the desired vessel caliber. A need therefore continues to exist for an expandable stent that can expand to the desired diameters of the trunk or main vessel portion and side branch portion of a bifurcated blood vessel, and that can also preserve a more natural blood flow at the bifurcation, without blocking flow to an unstented side branch of the bifurcation of the blood vessel to be treated. The present invention solves these and other problems, as will be shown.

SUMMARY OF THE INVENTION

Briefly, and in general terms, the present invention provides for a self-expanding stent assembly formed of discrete stent sections expandable to different diameters to accommodate a trunk or main vessel portion and one or more side branch portions of a bifurcated blood vessel. The discrete stent sections are spaced apart by a gap allowing blood flow between the sections from the trunk or main vessel portion to the side branch portions of the bifurcated blood vessel, and are connected together by one or more longitudinal spines. The stent assembly is adapted to be placed within bifurcated blood vessels at the point of bifurcation, with a larger section adapted to be disposed within the main body or trunk or main vessel portion of the bifurcation, and one or more smaller sections adapted to be disposed within one or more of the branches of the bifurcated blood vessel.

The stent assembly can be placed with a delivery system into and across a bifurcation, and can be oriented so that when the stent is deployed, the stent assembly will have the larger diameter stent section within the larger main body of the vessel, a smaller diameter stent section within the desired side branch, and the gap between the sections being positioned at the ostium of the opposing side branch vessel.

The invention accordingly provides for a self-expanding stent assembly to be implanted in a bifurcated vessel having a main vessel and one or more side-branch vessels connected to the main vessel adjacent to a bifurcation between the main vessel and the side branch vessels. In one presently preferred embodiment, the stent assembly includes a first expandable stent member adapted to be disposed and deployed in the main vessel, a second expandable stent member adapted to be disposed and deployed in one of the side branch vessels, and at least one longitudinal spine member connecting the first expandable stent member and the second expandable stent member together at one side of the first and second stent members. In a presently preferred aspect, the first and second stent members are

unconnected at the opposing sides of the first and second stent members. In another presently preferred aspect, the first and second stent members are spaced apart by a gap allowing blood flow between the first and second stent members from the main vessel to the side branch vessels of the bifurcated blood vessel. The gap is preferably positioned at the ostium of the other side branch vessel. The first and second stent members preferably have a first diameter in an unexpanded configuration for delivery in a body lumen, and a second diameter that is larger than the first diameter in an expanded configuration, and the second stent member second diameter in the expanded configuration is smaller than the second diameter in the expanded configuration of the first stent member.

In one presently preferred embodiment, the first and second stent members are each expandable cylindrical members. In another presently preferred embodiment, the first stent member is an expandable split tubular member with a semi-circular transverse cross-section, and the second stent member is an expandable cylindrical member. In an alternate preferred embodiment, the first stent member is an expandable cylindrical member, and the second stent member is an expandable split tubular member with a semi-circular transverse cross-section. The stent members of the stent assembly are preferably formed from a self-expanding material so that the first and second stent members expand from a first configuration for delivery through a body lumen to a second expanded configuration for implantation in the bifurcated blood vessel.

These and other aspects and advantages of the invention will become apparent from the following detailed description and the accompanying drawings, which illustrate by way of example the features of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a first embodiment of a self-expanding stent assembly according to the present invention;

Fig. 2 is a plan view of the self-expanding stent assembly of Fig. 1 deployed and disposed in a bifurcated vessel;

Fig. 3 is a cross-sectional view taken along line 3-3 of Fig. 1;

Fig. 4 is a cross-sectional view taken along line 4-4 of Fig. 2;

Fig. 5 is perspective view of a second embodiment of a self-expanding stent assembly according to the present invention;

Fig. 6 is a plan view of the self-expanding stent assembly of Fig. 5 deployed and disposed in a bifurcated vessel;

Fig. 7 is a cross-sectional view taken along line 7-7 of Fig. 5;

Fig. 8 is a cross-sectional view taken along line 8-8 of Fig. 6;

Fig. 9 is a plan view of a variation of the self-expanding stent assembly of Fig. 1 deployed and disposed in a bifurcated vessel; and

Fig. 10 is a plan view of a variation of the self-expanding stent assembly of Fig. 5 deployed and disposed in a bifurcated vessel.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

While a number of approaches to stenting of a bifurcated vessel have been proposed, it has commonly been difficult to place stents at a bifurcation and precisely control the spacing between multiple stents at or around the bifurcation of bifurcated blood vessels to allow for proper blood flow at the bifurcation. Since the branches of a bifurcation often differ significantly in diameter, an expandable stent that can expand to the desired diameters of the main vessel portion and side branch portions of a bifurcated blood vessel, and that can preserve a more natural blood flow at the bifurcation is needed.

As is illustrated in the drawings, the invention is accordingly embodied in a self-expanding stent assembly 20 adapted to be implanted in a bifurcated vessel 22, such as a blood vessel having a trunk or main vessel portion 24, a first side-branch vessel 26, and a second side-branch vessel 28 connected to the main vessel adjacent to a bifurcation 30 between the main vessel and the side branch vessel. In a first preferred embodiment illustrated in Figs. 1-4, the self-expanding stent assembly preferably includes a first expandable cylindrical stent member 32 having a longitudinal axis 34, a distal end 36, and a proximal end 38, and the first expandable cylindrical stent member is preferably adapted to be disposed and deployed in the main vessel. The self-expanding stent assembly also preferably includes a second expandable cylindrical stent member 42 having a longitudinal axis 44, a distal end 46 and a proximal end 48, and the second expandable cylindrical stent member is adapted to be disposed and deployed in one of the side branch vessels. In order to allow the stent assembly to be introduced through a body lumen such as the vasculature, the first and second cylindrical stent members have a first, smaller diameter in an unexpanded configuration, and a second, larger diameter in an expanded configuration. In a presently preferred embodiment, the second

cylindrical stent member second diameter in the expanded configuration is smaller than the second diameter in the expanded configuration of the first cylindrical stent member.

At least one longitudinal spine member 50 preferably connects the first expandable cylindrical stent member and the second expandable cylindrical stent member together at one side 52 of the first and second cylindrical stent members. For proper alignment of the first and second cylindrical stent members of the stent assembly, the first and second cylindrical stent members are preferably connected by a plurality of longitudinal spines. The second cylindrical stent member is preferably adapted to be disposed and deployed in the first side branch vessel, with the first and second cylindrical stent members spaced apart by a gap 53. The gap is preferably positioned at the ostium 54 of the second side branch vessel, to allow blood flow between the first and second cylindrical stent members from the main vessel to the side branch vessels of the bifurcated blood vessel. The first and second cylindrical stent members are preferably not connected together by longitudinal spines at the opposing side 56 of the first cylindrical stent member, to allow the longitudinal spines connecting the stent members together at side 52 to flex so that the stent members can move to have an appropriate angular relationship to each other to fit the main and side branch vessels when the stent members are disposed and deployed within the bifurcated blood vessel.

In a presently preferred implementation, the first and second cylindrical stent members are constructed of cylindrical, circumferentially extending strut members 58 connected together with longitudinal connector members 60 that space the circumferential strut members from adjacent circumferential strut members a predetermined, desired distance. The cylindrical, circumferentially extending strut members typically have an undulating or serpentine pattern, although other similar shapes and means for connecting the strut members may also be suitable. As will be further explained below, the first and second cylindrical stent members are preferably formed from a self-expanding material so that the first and second cylindrical stent members expand from a first unexpanded configuration having a smaller diameter for delivery through a body lumen to a second expanded configuration having a larger diameter for implantation in the bifurcated blood vessel.

In a second preferred embodiment illustrated in Figs. 5-8, a self-expanding stent assembly 70 is adapted to be implanted in a bifurcated vessel 72 having a main vessel portion 74, a first side-branch vessel 76, and a second side-branch vessel 78 connected to the main vessel adjacent to a bifurcation 80 between the main vessel and the side branch vessel. The

self-expanding stent assembly includes an expandable channel or U-shaped stent member 82 having a split tubular shape with a semi-circular transverse cross-section, having a longitudinal axis 84, a distal end 86, a proximal end 88, and the expandable channel-shaped stent member is preferably adapted to be disposed and deployed in the main vessel. The self-expanding stent assembly also includes an expandable cylindrical stent member 92 having a longitudinal axis 94, a distal end 96 and a proximal end 98, and the expandable cylindrical stent member is adapted to be disposed and deployed in one of the side branch vessels. The expandable channel-shaped stent member has a first diameter in an unexpanded configuration for delivery in a body lumen, and a second diameter larger than the first diameter in an expanded configuration, and the cylindrical stent member has a first diameter for delivery in a body lumen in an unexpanded configuration, and a second diameter larger than the first diameter in an expanded configuration. The cylindrical stent member second diameter in the expanded configuration is preferably smaller than the second diameter in the expanded configuration of the first channel-shaped stent member.

At least one longitudinal spine member 100 connecting the first expandable stent member and the expandable cylindrical stent member together at one side 102 of the split tubular stent and cylindrical stent members. Preferably a plurality of longitudinal spines are provided. The second cylindrical stent member is preferably adapted to be disposed and deployed in the first side branch vessel, with the split tubular stent and cylindrical stent members being spaced apart by a gap 103. The gap is preferably positioned at the ostium 104 of the second side branch vessel, to allow blood flow between the split tubular stent and cylindrical stent members from the main vessel to the side branch vessels of the bifurcated blood vessel. The split tubular stent and cylindrical stent members are preferably not connected together by longitudinal spines at the opposing side 106 of the split tubular stent and cylindrical stent members, to allow the longitudinal spines connecting the stent members together at side 102 to flex so that the stent members can move to have an appropriate angular relationship to each other to fit the main and side branch vessels when the stent members are disposed and deployed within the bifurcated blood vessel.

The split tubular stent and cylindrical stent members in the foregoing embodiments are currently preferably constructed of cylindrical, circumferentially extending strut members 108 connected together with longitudinal connector members 110 that space the circumferential strut members from adjacent circumferential strut members a predetermined distance. The

cylindrical, circumferentially extending strut members typically have an undulating or serpentine pattern, although other similar shapes and means for connecting the strut members may also be suitable. As will be further explained below, the split tubular stent and cylindrical stent members are formed from a self-expanding material so that the split tubular stent and cylindrical stent members expand from a first smaller diameter for delivery through a body lumen to a second expanded diameter for implantation in the bifurcated blood vessel.

As is illustrated in Fig. 9, in a presently preferred variant of the embodiment of Figs. 1-4, and in which like elements are identified by like reference numerals, a third cylindrical stent member 112 is provided that is similar to the second cylindrical stent member. The third cylindrical stent member has a diameter smaller than that of the first cylindrical stent member and is adapted to be disposed and deployed in a second side branch vessel. The third cylindrical stent member preferably is connected to the first, larger diameter cylindrical stent member at the opposing side 114 of the first, larger diameter cylindrical stent member by at least one longitudinal spine member 50. The first and third cylindrical stent members are also preferably spaced apart by a gap 53 adapted to be positioned at the ostium 54 of the first side branch vessel, to allow blood flow between the first and third cylindrical stent members from the main vessel to the side branch vessels of the bifurcated blood vessel. The first and third cylindrical stent members are preferably not connected together by longitudinal spines at the opposing side 116 of the third cylindrical stent member, to allow the longitudinal spines connecting the stent members together at side 114 to flex so that the stent members can move to have an appropriate angular relationship to each other to fit the main and side branch vessels when the stent members are disposed and deployed within the bifurcated blood vessel.

Referring to Fig. 10, in a presently preferred variant of the embodiment of Figs. 5-8, the self-expanding stent assembly 120 is adapted to be implanted in a bifurcated vessel 122 having a main vessel portion 124, a first side-branch vessel 126, and a second side-branch vessel 128 connected to the main vessel adjacent to a bifurcation 130 between the main vessel and the side branch vessel. The self-expanding stent assembly includes a first expandable cylindrical stent member 132 having a longitudinal axis 134, a distal end 136 and a proximal end 138, and the expandable cylindrical stent member is adapted to be disposed and deployed in the main branch vessel. The self-expanding stent assembly also includes an expandable channel-shaped stent member 142 having a split tubular shape, having a longitudinal axis 144, a distal end 146, and a proximal end 148. The expandable channel-shaped stent member is

preferably adapted to be disposed and deployed in one of the side branch vessels. The self-expanding stent assembly also includes a second expandable cylindrical stent member 152 having a longitudinal axis 154, a distal end 156 and a proximal end 158, and the expandable cylindrical stent member is adapted to be disposed and deployed in the other side branch vessel.

At least one longitudinal spine member 160 connects the first expandable cylindrical stent member and the expandable channel-shaped stent member together at one side 162 of the channel-shaped stent and cylindrical stent members, and at least one longitudinal spine member connects the first expandable cylindrical stent member and the second expandable cylindrical stent members together at the opposing side 164 of the first expandable cylindrical stent member and the second expandable cylindrical stent members. The first expandable cylindrical stent member and the expandable channel-shaped stent member, as well as the first and second cylindrical stent members, are also preferably spaced apart by a gap 166 adapted to be positioned at the ostia of the side branch vessels, to allow blood flow from the main vessel to the side branch vessels of the bifurcated blood vessel. The first expandable cylindrical stent member and the expandable channel-shaped stent member are preferably not connected together by longitudinal spines at the opposing side of the expandable channel-shaped stent member, and the first and second cylindrical stent members are preferably not connected together by longitudinal spines at the opposing side of the second cylindrical stent member, to allow the longitudinal spines connecting the stent members together to flex to allow the stent assembly to fit the main and side branch vessels.

In each of the foregoing embodiments and variants of the embodiment, the bifurcated stent assembly is self-expanding, being formed from a shape memory material, such as a nickel-titanium alloy having shape memory properties. The self-expanding bifurcated stent will remain passive in its martensitic state when its temperature remains below the transition temperature of the shape memory alloy. In this case, the transition temperature is typically below normal body temperature, or about 98.6°F, and in a preferred embodiment the transition temperature at which the self-expanding stent expands from the unexpanded configuration to the expanded configuration is approximately room temperature. Thus, when the shape memory material of the self-expanding bifurcated stent is exposed to normal body temperature upon insertion into a guiding catheter, the self-expanding bifurcated stent will transition to its austenitic state, and if not constrained by a retaining sheath, can expand radially outwardly to

assume a preformed, desired expanded state. Other shape-memory materials such as stress-induced martensite (SIM) alloys, which transform into martensite upon the application of stress such as a compressive load, and return to their austenitic, preformed state when the stress is removed may also be suitable for forming the self-expanding bifurcated stent. In one presently preferred embodiment, the split tubular stent and cylindrical stent members can be formed by laser cutting of appropriately dimensioned tubes of nickel titanium alloy that are heat treated to have shape memory. The spines that are used to connect the split tubular stent and cylindrical stent members together can be formed from any of a number of materials including, but not limited to, stainless steel alloys, nickel-titanium alloys, tantalum, tungsten, or the like, and can be connected to the split tubular stent and cylindrical stent members by welding, soldering, adhesive, or the like.

It will be apparent from the foregoing that while particular forms of the invention have been illustrated and described, various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

WHAT IS CLAIMED IS:

1. A self-expanding stent assembly for implanting in a bifurcated vessel having a main vessel and a side-branch vessel connected to the main vessel adjacent a bifurcation between the main vessel and the side branch vessel, comprising:

a first expandable stent member having a longitudinal axis, a distal end and a proximal end, said first expandable stent member being adapted to be disposed and deployed in the main vessel;

a second expandable stent member having a longitudinal axis, a distal end and a proximal end, and said expandable second stent member being adapted to be disposed and deployed in the side branch vessel; and

at least one longitudinal spine member connecting said first expandable stent member and said expandable second stent member together at one side of said first and second stent members.

2. The self-expanding stent assembly of Claim 1, wherein said first stent member has an unexpanded configuration for delivery in a body lumen, and an expanded configuration; said second stent member has an unexpanded configuration, and an expanded configuration; and said second stent member expanded configuration is smaller than said expanded configuration of said first stent member.

3. The self-expanding stent assembly of Claim 1, wherein said first and second stent members are unconnected at the opposing side of said second stent member.

4. The self-expanding stent assembly of Claim 1, wherein said bifurcated blood vessel has first and second side branch vessels, and said second stent member is adapted to be disposed and deployed in said first side branch vessel, said first and second stent members being spaced apart by a gap allowing blood flow between said first and second stent members from the main vessel to the side branch vessels of the bifurcated blood vessel, said gap being adapted to be positioned at the ostium of said second side branch vessel.

5. The self-expanding stent assembly of Claim 1, wherein said first and second stent members are formed from a self-expanding material so that said first and second stent members expand from a first smaller diameter for delivery through a body lumen to a second expanded diameter for implantation in said bifurcated blood vessel.

6. The self-expanding stent assembly of Claim 1, wherein said first stent member comprises an expandable cylindrical stent member, and said second stent member comprises an expandable cylindrical stent member.

7. The self-expanding stent assembly of Claim 1, wherein said first stent member comprises an expandable split tubular stent member, and said second stent member comprises an expandable cylindrical stent member.

8. The self-expanding stent assembly of Claim 1, wherein said first stent member comprises an expandable cylindrical stent member, and said second stent member comprises an expandable split tubular stent member.

9. A self-expanding stent assembly for implanting in a bifurcated vessel having a main vessel and a side-branch vessel connected to the main vessel adjacent a bifurcation between the main vessel and the side branch vessel, comprising:

a first expandable cylindrical stent member having a longitudinal axis, a distal end and a proximal end, said first expandable cylindrical stent member being adapted to be disposed and deployed in the main vessel;

a second expandable cylindrical stent member having a longitudinal axis, a distal end and a proximal end, said expandable second cylindrical stent member being adapted to be disposed and deployed in the side branch vessel; and

at least one longitudinal spine member connecting said first expandable cylindrical stent member and said expandable second cylindrical stent member together at one side of said first and second cylindrical stent members.

10. The self-expanding stent assembly of Claim 9, wherein said first cylindrical stent member has an unexpanded configuration and an expanded configuration; said second cylindrical stent member has an unexpanded configuration and an expanded configuration; and said second cylindrical stent member expanded configuration is smaller than the expanded configuration of said first cylindrical stent member.

11. The self-expanding stent assembly of Claim 9, wherein said first and second cylindrical stent members are unconnected at the opposing side of said second cylindrical stent member.

12. The self-expanding stent assembly of Claim 9, wherein said bifurcated blood vessel has first and second side branch vessels, and said second cylindrical stent member is adapted to be disposed and deployed in said first side branch vessel, said first and second

cylindrical stent members being spaced apart by a gap allowing blood flow between said first and second cylindrical stent members from the main vessel to the side branch vessels of the bifurcated blood vessel, said gap being adapted to be positioned at the ostium of said second side branch vessel.

13. The self-expanding stent assembly of Claim 9, wherein said first and second cylindrical stent members are formed from a self-expanding material so that said first and second cylindrical stent members expand from a first smaller diameter for delivery through a body lumen to a second expanded diameter for implantation in said bifurcated blood vessel.

14. A self-expanding stent assembly for implanting in a bifurcated vessel having a main vessel and a side-branch vessel connected to the main vessel adjacent a bifurcation between the main vessel and the side branch vessel, comprising:

an expandable split tubular stent member having a longitudinal axis, a distal end and a proximal end;

an expandable cylindrical stent member having a longitudinal axis, a distal end and a proximal end; and

at least one longitudinal spine member connecting said expandable split tubular stent member and said expandable cylindrical stent member together at one side of said expandable split tubular stent member and said expandable cylindrical stent member.

15. The self-expanding stent assembly of Claim 14, wherein said expandable split tubular stent member is adapted to be disposed and deployed in the main vessel, and said expandable cylindrical stent member is adapted to be disposed and deployed in the side branch vessel.

16. The self-expanding stent assembly of Claim 15, wherein said expandable split tubular stent member has an unexpanded configuration for delivery in a body lumen, and an expanded configuration; said expandable cylindrical stent member has an unexpanded configuration for delivery in a body lumen and an expanded configuration; and said expandable cylindrical stent member expanded configuration is smaller than the expanded configuration of said expandable split tubular stent member.

17. The self-expanding stent assembly of Claim 14, wherein said expandable cylindrical stent member is adapted to be disposed and deployed in the main vessel, and said expandable split tubular stent member is adapted to be disposed and deployed in the side branch vessel.

18. The self-expanding stent assembly of Claim 17, wherein said expandable cylindrical stent member has an unexpanded configuration for delivery in a body lumen, and an expanded configuration; and said expandable split tubular stent member has an unexpanded configuration for delivery in a body lumen and an expanded configuration; and said expandable split tubular stent member expanded configuration is smaller than said expanded configuration of said expandable cylindrical stent member.

19. The self-expanding stent assembly of Claim 14, wherein said bifurcated blood vessel has first and second side branch vessels, said cylindrical stent member is adapted to be disposed and deployed in said first side branch vessel, and said expandable split tubular stent member and said expandable cylindrical stent member are spaced apart by a gap allowing blood flow between said expandable split tubular stent member and said expandable cylindrical stent member from the main vessel to the side branch vessels of the bifurcated blood vessel, said gap being adapted to be positioned at the ostia of said side branch vessels.

20. The self-expanding stent assembly of Claim 14, wherein said expandable split tubular stent member and said expandable cylindrical stent member are formed from a self-expanding material.

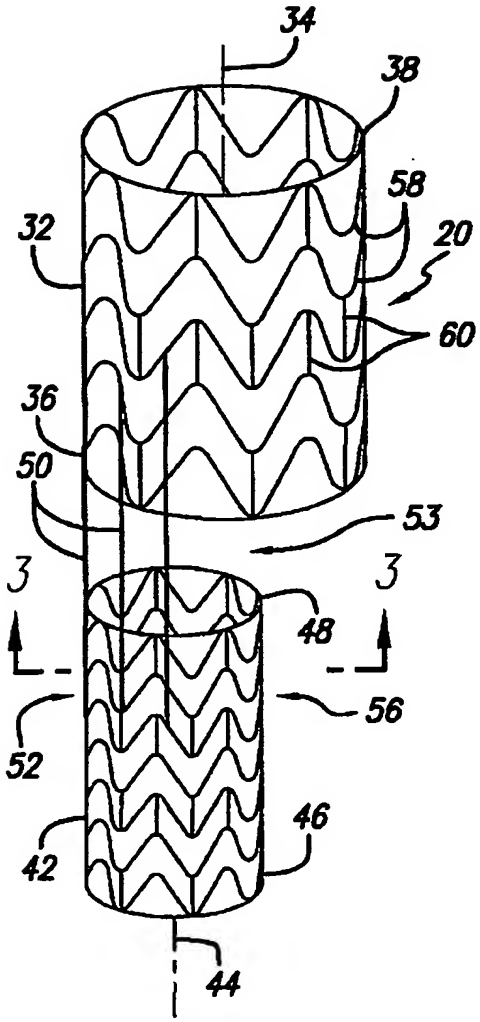

FIG. 1

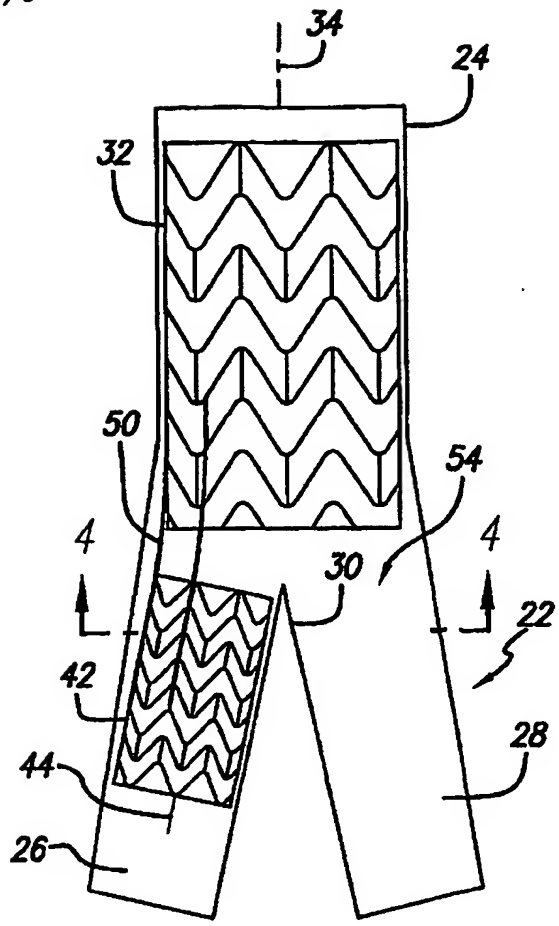

FIG. 2

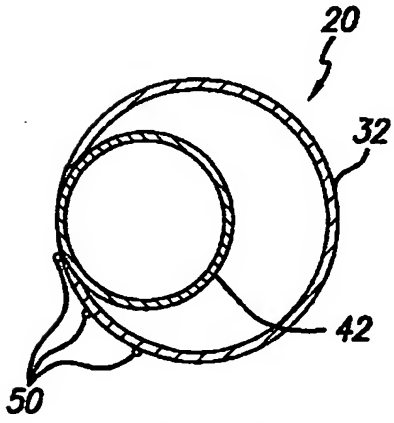

FIG. 3

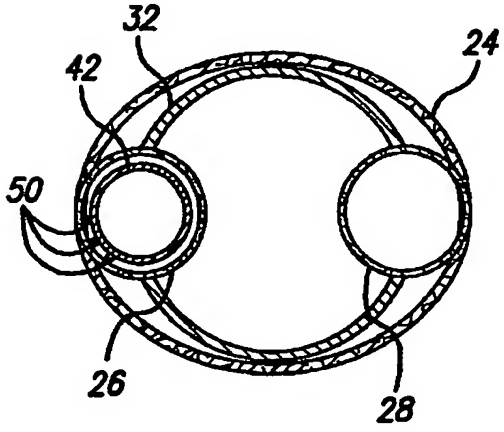

FIG. 4

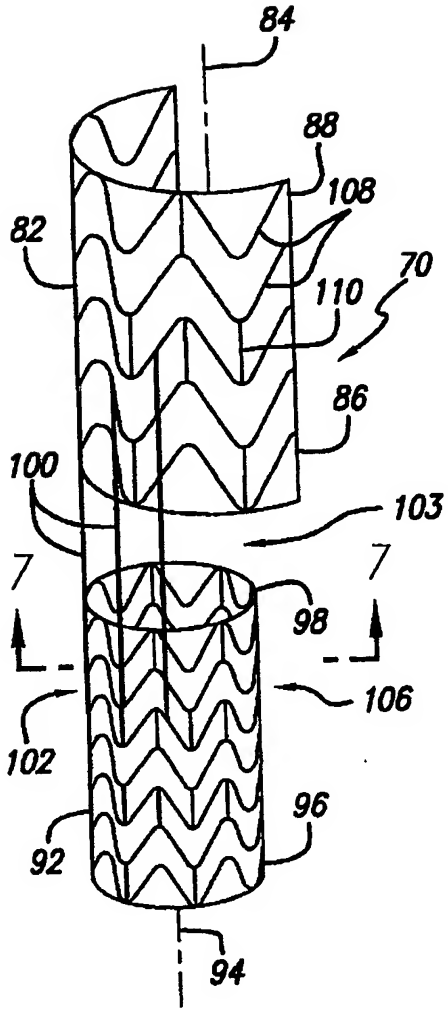

FIG. 5

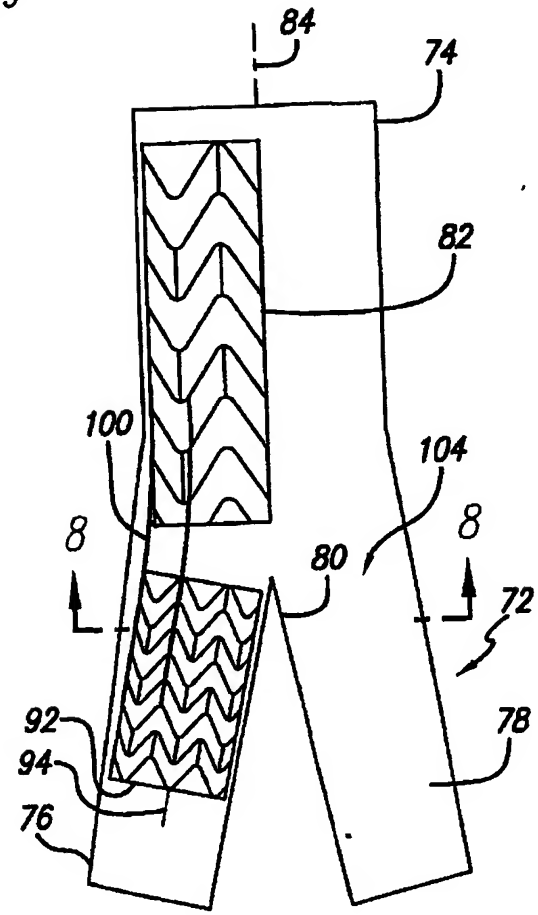

FIG. 6

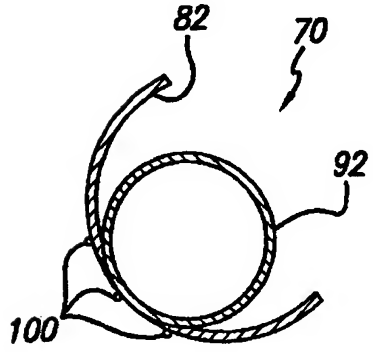

FIG. 7

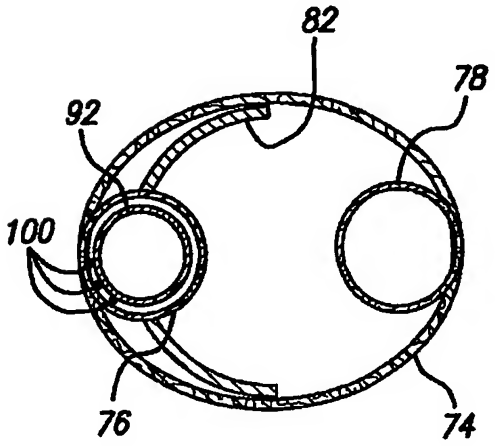

FIG. 8

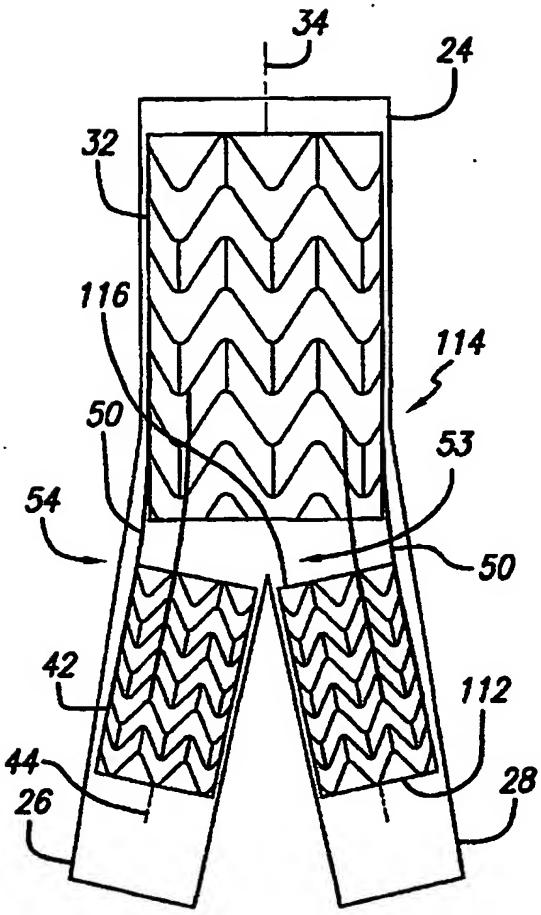
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FIG. 9

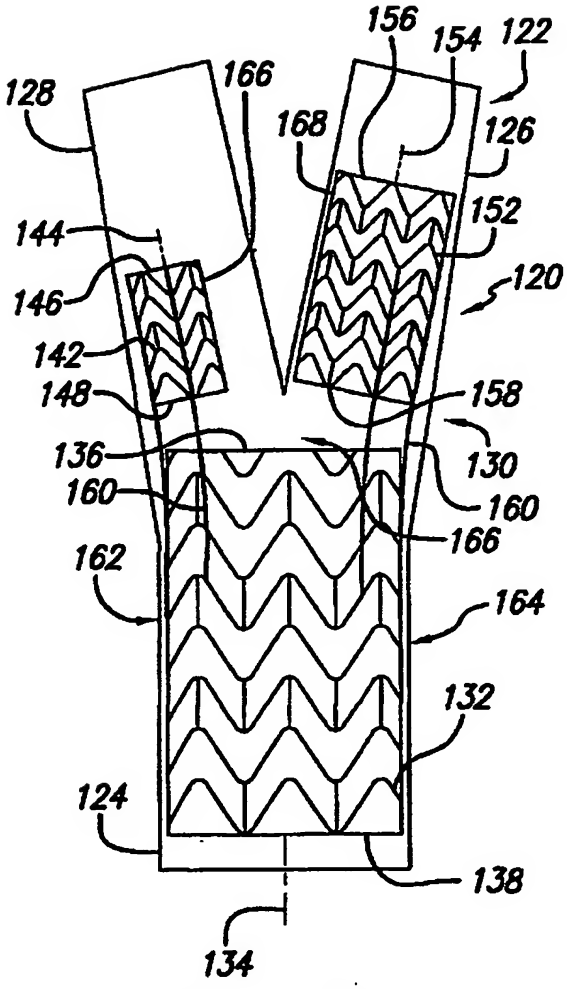
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FIG. 10

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 994 071 A (MACGREGOR DAVID C) 19 February 1991 (1991-02-19) column 5, line 39 - line 42; figure 1	1-6,9-13
X	WO 99 58084 A (UFLACKER RENAN) 18 November 1999 (1999-11-18) claims; figures	1-6, 9-11,13
X	WO 99 40873 A (PENN IAN M ;RICCI DONALD R (CA); MAROTTA THOMAS R (CA); SHUKOV GEO) 19 August 1999 (1999-08-19) page 18, line 21 -page 19, line 16; claim 13; figures 20-24	1-5,7, 14,15, 17,20
X	US 5 782 906 A (MARSHALL PAUL ET AL) 21 July 1998 (1998-07-21) the whole document	1-4,6, 9-12

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
5 September 2001	13/09/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Neumann, E

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96 34580 A (DIBIE ALAIN) 7 November 1996 (1996-11-07) page 5, line 9 - line 14; figures	1-4,6, 9-12

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